

LS40/60 Freeze Dryer

Instruction Manual

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Declaration of Conformity

Manufacturer's Name: Severn Science Ltd

Manufacturer's Address: 5 Short Way
Thornbury, Bristol
BS35 3UL England

Model / Serial No:

Date of Issue:

Severn Science Limited hereby declares that the above product conforms with the essential protection requirements of:

Low Voltage Directive 73/23/EEC amended by 93/68/EEC.

EMC Directive 89/336/EEC as amended by 92/31/EEC.

Machinery Directive 89/392/EEC

by application of the following standards:

Safety: BS EN61010, 1993

Safety: BS EN 292-1, -2 : 1991

Emissions: BS EN 50081-2: 1994

Immunity: BS EN 50082-2 : 1995

Signed on behalf of Severn Science Limited
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1.0 INTRODUCTION

1.1 SCOPE

This manual provides installation and operation instructions for the *LYOSCIENCE* LS40 and LS60 freeze dryers. The manual and all accompanying documentation must be read before operating the equipment.

Important safety information is highlighted as **WARNING** and **CAUTION** instructions; you must obey these instructions. The use of WARNINGS and CAUTIONS are defined in the general safety section.

1.2 GENERAL SAFETY

WARNING: Warnings are given where failure to observe the instruction could result in injury or death to persons.

CAUTION: Cautions are given where failure to observe the instruction could damage to the equipment, associated equipment or process. Refer to the accompanying manufacturers' instruction manuals for the technical data on individual components.

See Appendix 1 for list of Instruction Manuals.

WARNING: Sodium Azide Explosion Hazard

Sodium Azide, which is sometimes used in the freeze-drying process, is a toxic and (when dry) highly explosive material. In the process of pumping product containing this chemical, a reaction can occur in the presence of heavy metals (copper, lead, zinc and cadmium). The resulting reaction is the formation of heavy metal azides that are highly unstable, and which present a very severe explosion hazard. **Standard LS40 and LS60 freeze dryers are not suitable for use with Sodium Azide.** Please contact Severn Science if you wish to use Sodium Azide; the equipment can be modified by the manufacturer for safe operation with Sodium Azide if required.

1.3 GENERAL DESCRIPTION

1.3.1 FREEZE DRYING - BASIC PRINCIPLES

Freeze drying is a method used to dehydrate heat sensitive materials via a process involving the sublimation of any water content (in the form of ice) under vacuum conditions. The process can be subdivided into three (3) stages; freezing, primary drying, where the bulk of the water content is removed by sublimation, and secondary drying where residual bound water is removed at higher temperatures. The *LS range* of freeze dryers is capable of automatically performing all these functions in a controlled and reproducible manner.

The equipment consists of a large vacuum drying chamber mounted directly above a refrigerated condenser with integral vacuum pump. The drying chamber contains up to five refrigerated shelves that can be moved up and down via an electrically operated ram for stoppering processes. Both condenser and drying chambers are fitted with their own refrigeration systems, specified for either high temperature (denoted model LS40) or low temperature (model LS60) use. The temperature of the product shelves used in the LS40 can be controlled between +60°C and -40°C whereas shelf temperatures can be varied between +60°C and -60°C for the LS60 version. Both systems have a compact footprint allowing the equipment to be moved through standard sized doorways. Commissioning is simple and straightforward, requiring no external services other than mains power. All components are housed inside a free-standing cabinet with detachable inspection panels at the front, rear and sides for easy maintenance.

1.3.2 THE CONDENSER UNIT

The condenser unit consists of a cylindrical chamber (290 X 620 mm) with an inlet port situated near the front of the chamber and a 25 mm outlet port positioned at the rear of the chamber. The chamber walls are cooled directly by an integral CFC free refrigeration system mounted in the base of the unit. During freeze drying, water vapour that is extracted from the product, is condensed onto the chamber walls, resulting in the formation of an ice 'plug'. The chamber has a total ice capacity of ~15Kg between defrost cycles. The minimum temperature of the chamber wall under vacuum conditions with no load applied is -45°C and -80°C for the LS40 and LS60 models respectively.

The condenser inlet is connected to the drying chamber via an electrically actuated high vacuum butterfly valve. The chamber outlet is connected to the inlet of an RV12 vacuum pump. A transparent perspex door at the front of the condenser allows the operator to inspect the ice plug and provides convenient access for cleaning purposes.

The chamber is automatically defrosted when the condenser refrigeration system is turned off. Defrosting is assisted using a band heater that is wound round the external surface of the chamber. The ice can be removed as a solid plug after defrosting the chamber for ~ 1 hr. Any ice that has melted can be removed via a solenoid operated drain valve in the bottom of the chamber or removed by the operator during general maintenance.

A two stage oil-sealed rotary vacuum pump (RV12) mounted on the base of the unit is used to evacuate both condenser and drying chambers. The pump outlet is fitted with a mist filter to prevent oil mist escaping to the atmosphere. The exhaust of the filter is piped to a stub connection at the rear of the freeze dryer, which in turn should be connected to the user's exhaust extraction system.

Oil collected in the mist filter is continuously returned into the gas ballast port of the pump.

The condenser temperature and pressure is monitored with a PT100 and a pirani gauge respectively; data can be continuously displayed on the touch screen if required.

1.3.3 THE DRYING CHAMBER

The drying chamber is mounted directly above the condenser unit (refer to figure 1). The chamber is fitted with up to five temperature controlled product shelves, a refrigeration / heater plant with heat transfer fluid circuit and a shelf stoppering mechanism. A transparent perspex door at the front of the chamber allows the operator to inspect the product during the freeze drying process and provides access for loading and unloading.

Each shelf contains an internal network of channels through which the heat transfer fluid can flow freely and continuously. Heat is extracted or introduced into the fluid via the refrigeration / heater plant and is then distributed to each shelf in parallel through

a common manifold and liquid re circulating pump. Sensors in the fluid circuit provide feedback for closed loop temperature control. Temperature control is achieved by modulating the flow of heated and cooled fluid with the use of solenoid operated isolation valves in the fluid circuit.

The shelves are mechanically linked to an electrically actuated ram with variable torque drive. The ram moves the shelves up and down allowing automatic stoppering of vials under vacuum and other controlled atmospheres. Operation of the ram is interlocked with safety switches on the front perspex door ensuring that the actuating mechanism is disabled when the door is opened.

WARNING: The interlock switches should never be removed or tampered with.

1.3.4 CONTROL SYSTEM

The freeze dryer is controlled by an on-board microprocessor with touch screen display (see figure 1). Freeze drying cycles (process recipes) can be programmed directly using the touch screen (refer to section 5). The general layout of the controller is shown in figure 2. All freeze drying segments (e.g., primary and secondary drying, end point determination, backfill and stoppering) can be fully automated if required with an almost limitless number of temperature / pressure profiles with defined ramp rates, dwell points and times. Programs can be saved and retrieved for use at a later date, if required. The operator can access all status and control functions from the display screens and system data can be reviewed in real time or downloaded onto 1.44Mb floppy disks via the integral disk drive.

The control system is password protected for various levels of access.

An emergency stop button is situated on the front control panel, for disabling the stoppering drive in cases of emergency.

2.0 TECHNICAL DATA

Table 1: Technical Specification

FUNCTION	MODEL	PERFORMANCE
Minimum condenser temperature (@ 25°C ambient)	LS40 LS60	-45°C -80°C
Minimum shelf temperature (@ 25°C ambient)	LS40 LS60	-40°C -60°C
Shelf cool down times (fitted with 3 product shelves). Temperatures measured on shelves.	LS40 (to -35°C) LS40 (to -40°C) LS60 (to -55°C) LS60 (to -60°C)	100 minutes 220 minutes 130 minutes 160 minutes
Maximum shelf temperature	LS40/60	60°C
Temperature uniformity (between shelves)	LS40/60	± 0.6°C
Temperature uniformity (across each shelf)	LS40/60	± 0.3°C
Temperature control	LS40/60	± 0.2°C
Condenser capacity	LS40/60	15 kg
Defrost time (for ice plug removal)	LS40/60	1 hour

Vacuum Pump 1. Type 2. Nominal Pumping speed 3. Pump down time (to 0.5 mbar)	LS40/60	Edwards RV12 12 m ³ /hr Approx 10 minutes
Vacuum Pump Oil	LS40/60	Ultragrade 19
Heat Transfer Fluid	LS40/60	Silicone M90.055.03
Electrical a) Supply b) Power rating (ambient temperature 20°C)	LS40/60 LS40 LS60	230V, 50Hz, 1 ph, or 110V, 60 Hz, 1 ph. 5.1 kW 6.9kW
Dimensions (w x h x d)	LS40/60	700 x 1906 x 950 mm
Weight	LS40/60	600 Kg
Shelf area a) Maximum (5 shelves) b) Standard (3 shelves)	LS40/60	0.85 m ² 0.51 m ²
Refrigerants	LS40 LS60	R404A R404A / R508B
Maximum ambient operating temperature (measured at inlet to heat exchangers)	LS40/60	30°C

3. 0 INSTALLATION

3.1 UNPACK AND INSPECT

Remove all packing material and protective covers from vacuum outlet port.

CAUTION: Remove all packing material before operating system.

If the equipment is damaged, notify your supplier and the carrier in writing within three days.

3.2 EQUIPMENT PLACEMENT

Locate the freeze dryer in the required position, ensuring that the floor is adequate to support the equipment and that due consideration is given to:

- a) Air flow for ventilation
- b) Access to framework panels.
- c) Adequate space for maintenance.

CAUTION: The ventilation holes in the framework panels must not be blocked or impeded in any way. If they are, overheating and damage may result.

CAUTION: Heat generated by the refrigeration compressors is significant. If the equipment is situated in a confined space it may be necessary to provide some

additional air flow / air conditioning to ensure that the temperature at the inlet to the refrigeration heat exchangers is kept below 30°C. Please consult with Severn Science for further details.

After placement, remove all panels to carry out initial inspection (see sections 3.3 and 3.4). The panels are fitted with lockable latches. To remove panels, unlock the latch using the key provided, press the top end of the latch lever closest to the key hole and lift bottom end of lever away from panel.

3.3 PREPARATION OF VACUUM PUMP

The vacuum pump is located on the base of the condenser unit. Both dryer and condenser chambers are dispatched from the factory under vacuum. To check vacuum integrity ensure that the two front perspex doors can not be easily opened. Only use moderate force. If either chamber is not under vacuum when supplied, contact Severn Science immediately.

3.3.1 CHECK PUMP OIL LEVEL

Check the sight glass located on the vacuum pump body (refer to manufacturer's literature). The oil level must be between the MAX and MIN level indicators.

3.3.2 VACUUM PUMP SETTINGS

The vacuum pump is configured at the factory with the following settings (see to manufacturers' literature).

- Gas ballast 1 (or 0 for some applications)
- High vacuum mode

Check that these setting have not been changed.

3.3.3 PUMP EXHAUST CONNECTION

The vacuum pump exhaust is internally ducted to a stub pipe located on the rear panel of the condenser unit. Exhaust gases must be ducted away for suitable disposal.

WARNING: Exhaust gases must be ducted away from the surrounding atmosphere if any pumped vapours present a possible health hazard .

WARNING: Do not obstruct any vacuum pump exhaust port (refer to manufacturer's manual before operation).

3.4 PREPARATION OF REFRIGERATION SYSTEM

The refrigeration plant in both condenser and drying units should be examined before use. First check that the refrigeration gas lines are not contaminated with moisture by examining the colour coded indicators (only applicable for LS40 models). If the indicators are yellow, do not use the equipment and contact Severn Science immediately.

The cooling circuit in the drying unit uses a heat transfer fluid (silicone oil). Check the chamber insulation for signs of oil leaks and confirm that the oil reservoir is approximately half full. The oil level in the reservoir can be checked again when the panels are refitted by comparison with the MIN / MAX levels on the panel viewing port. If the oil level is low, do not use the equipment and contact Severn Science immediately.

3.5 ELECTRICAL INSTALLATION

Ensure that all framework panels are refitted before connecting to any services.

WARNING: Failure to refit all panels prior to connecting to mains power may result in injury or death to the operator.

The freeze dryer is supplied with one (1) 32 amp plug. Connect this to suitable a socket.

CAUTION: The unit is factory configured for 230V single phase supply. Check that your voltage supply is compatible. The equipment will be damaged if it is connected to the wrong voltage supply.

4.0 OPERATION

4.1 POWER UP

Press the illuminated green “power” button located at the top left hand side of the front panel of the drying unit. Allow approximately 35 seconds for the control system to run its “power up” cycle. The *Severn Science* screen will appear on the display. Check that the emergency stop is in the unlocked position and press the blue reset button if it is illuminated to reactivate the stoppering mechanism ready for later use.

4.2 SECURITY CONTROL

The control system is password protected to ensure controlled access to freeze dryer functions and data. There are 3 user levels of entry :-

Locked level: This is the default level from power up and hence no password is required. At this level, the user can monitor the current status of the freeze dryer through a limited number of screens, but does not have the ability to make any parameter changes. The locked level is accessed by pressing the HOME button.

Operator Level: At the operator level, the user can start up and close down the refrigeration systems, load and run pre-configured programs and view the alarm history.

Supervisor Level: At the supervisor level the user has the same access compared with that of the operator level but can also create new programs, set up the end of program sequence, customise the data logging facility and acknowledge alarms.

To log on at the operator or supervisor levels, a user id and password are required.

To log on at the operator or supervisor levels first press the ACCESS button. The *Security Access* screen will appear displaying the current security level and separate fields for inputting the user identity and password. When either the **identity** or **password** fields are pressed a keypad will appear. The user inserts the relevant code and presses the green RETURN key (note: all codes are case sensitive). When both codes have been inputted the *Security Access* screen will again appear. To complete the access procedure the user presses the LOG ON button. The controller will automatically recognise the security codes and will allow the operator to enter at the relevant security level.

Screens and text are colour coded depending on the security level of the operator, as indicated in table 2.

Table 2. Screen and Text Colour Coding

Type	Appearance	Access
Fields	Blue figures/white background	NO
	Blue figures / yellow background	YES
Screen buttons	Greyed out wording	NO
	Black wording	YES

Users can be designated during commissioning by the Severn Science engineer or at any time after installation by following the procedure below:

- Log on as per the above procedure taking the id and password information from Table 3 (according to the level of access required).
- To personalise the password, select the PASSWD button (on the *Security Access* screen). Press the **password** field and type in the new password (case sensitive).
- Press the enter and OK buttons
- Re enter the password in the field provided and press OK

The new user can then log on using the new password at the designated security level.

Note: The id is not user adjustable.

Table 3. Additional id and Password codes

id	Password	Access Level
OP1	OP1	Operator
OP2	OP2	Operator
OP3	OP3	Operator
OP4	OP4	Operator
OP5	OP5	Operator
SUP1	SUP1	Supervisor
SUP2	SUP2	Supervisor
SUP3	SUP3	Supervisor
SUP4	SUP4	Supervisor
SUP5	SUP5	Supervisor

4.3 SWITCH ON CONDENSER

Security level : Operator or supervisor

Press the menu key on the printed keypad located below the screen (see figure 2) and select the HOME button. The *Home* screen will appear. Follow the instructions below to start the condenser.

- press the field showing **condenser defrost** on the left hand side of the screen (CONDENSER CHAMBER). From the options press 'CONDENSER RUNNING'.
- Press the green RETURN button.

The vacuum pump will temporarily switch on to seal the door and the condenser will then begin its cool down cycle. When a temperature of -60°C is reached, the vacuum pump will automatically switch on and both the refrigeration and vacuum pump will run continuously. The condenser is ready to use when it reaches a temperature relevant for the freeze drying process.

WARNING: Do not touch any part of the Condenser during the cooling process. The cold surfaces will cause tissue damage.

4.4 SWITCH ON SHELF REFRIGERATION

Security level : Operator or supervisor

Cooling of the shelves in the drying chamber is provided by a separate refrigeration system. To turn the shelf refrigeration system on, follow the instructions below:

- a) From the *Home* screen press the field showing **Refrigeration off** on the right hand side of the screen (DRYING CHAMBER). From the options press 'REFRIGERATION ON'.
- b) Press the green RETURN button.

The temperature of the shelves will now be controlled at the temperature shown in the **set point** field on the right hand side of the *Home* screen.

Note: The shelf temperature can be adjusted by inputting the appropriate value in the **set point** field. When the **set point** field is pressed a keypad will appear (see figure 2(d)). Insert the required value and press the green RETURN button.

WARNING: Do not touch the shelves during the cooling process. The cold surfaces will cause tissue damage.

4.5 LOADING THE PRODUCT

Security level : Operator or supervisor

The freeze dryer can be used for both vial and bulk drying. The number of shelves mounted in the drying chamber (ranging from 1 to 5) is factory set according to the user requirement. Inter shelf measurements and vial capacities for different shelf configurations are given in Table 4. The door to the drying chamber can be opened using the quarter turn handle.

Note: Do not use excessive force to open the chamber door. If the drying chamber is under vacuum (for instance when the freeze dryer is first delivered) it will not be possible to open the chamber door.

Note: To open the chamber door if the chamber is under vacuum, first vent the chamber, as follows (operator and supervisor access only):

- a) From the *Home* screen, press the field showing **vent closed** on the right hand half of the display (DRYING CHAMBER). From the options press 'VENT OPEN'.
- b) Press the green RETURN button.

Note: The system is interlocked so that the vent valve can not be opened unless the vacuum valve between the drying and condenser chambers is also closed. If it is necessary to close the vacuum valve, refer to section 7, Manual Operation.

After loading the product into the chamber, any pre loaded freeze drying programs can be run (see section 4.6 below), or new programs can be edited or created (section 5.0).

Table 4: Vial Capacity and Inter-shelf Distances

Vial Diameter (mm)	Vial Capacity			
	3 shelf	4 shelf	5 Shelf	Per Shelf
13.5	2808	3744	4680	936
22.0	1056	1408	1765	353
25.0	798	1064	1330	266
30.0	576	768	960	192
30.5	540	720	900	180
36.5	351			117
43.0	264			88

Number of Shelves	Maximum working height (mm)	Minimum working height (mm)
2	137	87
3	95	38
4	66	24
5	49	15

4.6 RUNNING A FREEZE DRYING CYCLE

Security level : Operator or supervisor

From a control viewpoint, a complete freeze drying cycle is typically split into two distinct phases; an initial program phase which controls the temperature and pressure profiles required during freezing and drying, followed by an optional end-of-program sequence (EPS) where the user can customise how the cycle is finished after initial drying is complete (e.g., stoppering, backfill etc.). This section describes how to run a program and how to select the required EPS (4.6.4).

There are three ways to run a program.

- Run a program now
- Run a program from a point
- Schedule a program to run from a time

4.6.1 RUN A PROGRAM NOW

To run a program, first load the required program from the list of stored recipes.

- Press the MENU printed key (see figure 2(a))
- Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.

- c) Press the PROGRAMS button. The *Load/Save Program* screen will be displayed.
- d) Press the **file name** field . A list of program names will appear in the Options Menu (see figure 2 (c)). From the list, press the name of the program to be loaded.

Note: When the equipment is first delivered there will only be one program template called Prog 1. Once loaded this can be edited as required (see section 5).

- e) Press the green RETURN key. The display returns to the *Load /Save Program* screen and the **file name** field now displays the name of the program that has been selected.
- f) Press the LOAD button. At this stage, the *Programmer* menu appears and the program name and status is displayed in the program panel.
- g) Press the RUN button. The program panel changes to green indicating that the program is now running. The time when the program is due for completion is also displayed together with a number that indicates the number of segments that have been completed (see figure 2). At the same time the *EPS* screen automatically appears, giving the operator the opportunity to review the End of Program Sequence.

The freeze dryer will automatically run each segment of the selected program until it is complete. On completion, the program panel will either display 'complete' or 'idle' depending on the end-of-program sequence (see section 4.6.4) .

Note : If the program panel does not change to green after pressing RUN, go to the *Status* screen to check for possible causes (see figure 3).

4.6.2 RUN A PROGRAM FROM A POINT

Select this function if you wish to run a program from a point other than the start point of the selected program.

- a) Press the MENU printed key
- b) Press the PROGRAMMER button. The *Programmer* menu will be displayed.
- c) Press the PROGRAMS button. The *Load/Save Program* screen will be displayed.
- d) Press the **file name** field . A list of program names will appear in the Options Menu (see figure 2(c)). From the list, press the name of the program to be loaded.
- e) Press the green RETURN key. The display returns to the *Load /Save* screen and the **file name** field now displays the name of the program that has been selected.

- f) Press the LOAD button. At this stage, the *Programmer* menu screen will appear. The program name and status will be displayed in the program panel in the top left hand corner of the screen.
- g) Press the RUN FROM button. A screen headed with the name of the program is loaded. The total running time for the program selected is displayed. Press the **Run From** field (default setting is 00:00:00) and input the time on the numeric keypad (in hours:minutes:seconds) after the start of the program when the program should run from. Press the green RETURN key when inputting is complete. Details of the segment which will be running when the program starts will then be shown in the lower half of the display.
- h) To run the program, press the RUN button. The *Programmer* menu will appear and the colour of the program panel changes to green (indicating that the program is running). The time when the program is due for completion is also displayed together with a number that indicates the number of segments that have been completed. At the same time the *EPS* screen is automatically displayed, giving the operator the opportunity to review the End of Program Sequence.

Note : If the program panel does not change to green after pressing RUN, go to the *Status* screen to check for possible causes (see figure 3).

4.6.3 SCHEDULING A PROGRAM

Scheduling a program allows the operator to set a time at which a program will start and run automatically.

- a) Press the MENU printed key
- b) Press the PROGRAMMER button. The *Programmer* menu will be displayed.
- c) Press the SCHEDULE button. The *Schedule Program* screen will be displayed.
- d) Press the **File Name** field. A list of program names will appear in the Options Menu (see figure 2(c)). From the list, press the name of the program to be loaded.
- e) Press the green RETURN key. The display returns to the *Schedule Program* screen and the **file name** field now displays the name of the program that has been selected.
- f) Press the **Start Date** field. Input the required start date on the numeric key pad (day:month:year). Press the green RETURN button.
- g) Press the **Start Time** field. Input the required start time on the numeric key pad (hours:minutes:seconds). Press the green RETURN button.
- h) To change the number of iterations (number of complete cycle to be performed sequentially), press the **Iterations** field. Input the required number and press the green RETURN button. Note: The default number of iterations is 1. Entering a value "0" will run the program continuously.

- i) Press the ACCEPT button. The program will automatically start at the date and time shown in green at the top of the screen.

4.6.4 END OF PROGRAM SEQUENCE (EPS)

The EPS function allows the user to select a method to complete the cycle after the initial freeze drying program is complete. EPS functions include automatic end point determination (EPD), secondary drying, backfill and stoppering. The functions are optional and can be activated manually if required. The *EPS* screen is accessed from the *Home* screen by pressing the EPS button.

- a) Automatic end point determination (EPD): This is an automatic pressure rise test that gives an indication of the state of dryness of the product at the end of the drying program. During EPD, the vacuum valve is first closed. The rate of pressure rise in the drying chamber is then monitored and automatically compared with a pre programmed user adjustable set point. If the rate exceeds the target value, the vacuum valve is re opened and drying continues at the last programmed temperature set point. Drying continues for a period of time determined by the user when initially setting up the EPD after which the pressure rise test is then repeated. The sequence (drying / test / drying) is repeated until the pressure rise test is within the target value or if the test is manually aborted.

Automatic end point determination can be selected or deselected from the *EPS* screen, by toggling between **YES** and **NO** on the field provided. Instructions to set the pass /fail limit and drying time are described in section 5.

- b) Secondary Drying: Secondary drying is typically used to remove bound water from the product after primary drying is complete. A secondary drying profile can be included in the initial program. However, if secondary drying is required after automatic end point determination (see above), then this part of the cycle must be programmed using the EPS facility.

Secondary drying can be selected or deselected from the *EPS* screen, by toggling between **YES** and **NO** on the field provided. Instructions to set the drying temperature and time are described in section 5.

- c) Automatic Backfill: This facility is used to inject controlled atmospheres into the equipment before stoppering and venting.

Automatic backfill can be selected or deselected from the *EPS* screen, by toggling between **YES** and **NO** on the field provided. Instructions to set the backfill pressure are described in section 5.

- d) Automatic Stoppering: Automatic stoppering is used to stopper vials after the freeze drying cycle is complete.

Automatic stoppering can be selected or deselected from the *EPS* screen, by toggling between **YES** and **NO** on the field provided.

CAUTION: When using the stoppering facility (automatic or manual), the stoppering jacks provided must be used. Instructions to set up the stoppering jacks are described in figure 4. Failure to do so may result in damage to the vial samples.

4.7 PROGRAM MONITORING

The program monitoring function allows the operator to review program status in real time. This can be viewed as a list or graphically using the monitor and Pre-Plot facilities.

4.7.1 MONITOR FACILITY

Security Level : Operator or Supervisor

To view the current program status, follow procedure below.

- a) Press the MENU printed key
- b) Press the PROGRAMMER button. The *Programmer* screen will appear.
- c) Press the MONITOR button. The *Current Program* screen will display information about the program as it is running. Information provided under the 'Program' heading includes:

Name :	(Program name)
Status :	(e.g., RUN, HOLD, etc)
Duration :	(total program length)
Completion :	(Time to complete program)
Iteration :	(Current program cycle /total number of cycles)

Information provided under the 'Segment' heading includes

Name :	(Segment name).
Time remaining :	(Time to complete current segment).

4.7.2 PRE-PLOT FACILITY

Security level: Operator or Supervisor

To view a summary of the program status in graphical form, follow the procedure below:

- a) Press the MENU printed key.
- b) Press the PROGRAMMER button. The *Programmer* screen will appear.
- c) Press the PRE-PLOT button. A graph will appear on the screen, headed with the title of the program in use. Process parameters are logged on the 'Y' axis as a

function of time ('X' axis). Actual and set point data is colour coded as per the legends displayed on the right hand side of the screen.

To review historical data and to zoom in on different parts of the graph, press the **OPTIONS** printed key (see figure 2(a)) followed by the **VIEW** button. Pan and Zoom controls then appear on the major axes (see figure 5). A cursor (dotted vertical line) will also appear on the right hand side of the screen. This can be dragged to any point on the graph. Actual data, corresponding to the point where the cursor intercepts the graph, is displayed in the legends.

4.7.3 TRENDS

The 'Trends' facility gives the user the ability to review all product and chamber information in graphical form. To view all trends follow the procedure below:

- a) Press the menu printed key.
- b) Press the **USER SCREENS** button. The *User Screens* menu will appear.
- c) Press the **TRENDS** button.
- d) Select the button according to the data that must be reviewed (Chamber Trends, Product Trends, Condenser Trends).

4.8 HOLDING A PROGRAM

The Hold facility is used to freeze the program if amendments to the program are needed after it has been initiated.

To Hold a program follow the sequence below:

- a) Press the green program panel in the top left hand corner of the screen (see figure 2(b)). The *Programmer* screen will appear.
- b) Press the **HOLD** button. The program panel will change to yellow and will read 'HELD'. The program finish time will be adjusted automatically according to the time the program is held. Amendments to the program can then be made as per section 5.0.

To restart a program:

- a) Press the yellow program panel in the top left hand corner of the screen. The *Programmer* screen will appear.
- b) Press the **RUN** button. The program panel will change to green and read 'RUN'.

4.9 ABORTING A PROGRAM

Security level : Operator or Supervisor.

To abort a program:

- a) Press the green program panel in the top left hand corner of the screen (see figure 2(b)). The *Programmer* screen will appear.

Press the ABORT button. The program will abort and the program panel will change to white and read 'IDLE'. The program can then be run again from the start or a new program loaded (see section 4.6).

4.10 STOPPERING

Stoppering can be pre programmed via the EPS facility (see section 4.6.4). Alternatively, shelves can be moved up and down by pressing the arrowed buttons located on the control panel and holding until the required shelf position is achieved.

Note:

Safety interlocks ensure that the shelves can only be operated when the front acrylic door to the drying chamber is closed.

CAUTION: Stoppering jacks must be fitted and positioned before attempting to stopper vials either manually or as part of a program. Ensure that the overall height of the stoppering jack is identical to the combined height of the product vial with a stopper fitted (in sealed position). For further instruction, refer to figure 4. Failure to fit the jacks may result in damage to the vials during the stoppering process.

Note: Activation of the emergency stop button mounted on the front panel will stop any movement of the shelves.

Note: Manual stoppering is not possible when a freeze drying cycle is in progress.

Note: To reactivate the stoppering system after the emergency stop button has been depressed, twist and release the stop button and press the blue 'reset' button.

WARNING: Activation of the emergency stop button does not isolate the electrical supply to the equipment.

4.11 REMOVING PRODUCT

Check that the freeze drying cycle is complete before attempting to remove the product (the Cycle Status on the *Home* screen will read 'Finished'). If the chamber is left under vacuum at the end of the cycle, product can be removed by first ensuring that the vacuum valve is closed and then manually venting the chamber. To vent the chamber follow the instructions below:

- a) From the Home screen, press the field showing vent closed on the right hand side of the display (DRYING CHAMBER). From the options, press 'VENT OPEN'.
- b) Press the green RETURN button.

If the chamber is automatically vented to atmospheric pressure at the end of the cycle, no further action is required before removing the product.

4.12 CONDENSER DEFROST

Security level : Operator or Supervisor

To turn the condenser off, press the field labelled 'CONDENSER RUNNING' from the *Home* screen. Select 'CONDENSER DEFROST' from the Options Menu followed by the green RETURN button.

Note:

- a) When CONDENSER DEFROST is selected the air admittance valve will open, the vacuum pump and refrigeration system will switch off and the defrost heater will activate. When a temperature of 25°C is reached, the defrost heater will automatically switch off.

The ice inside the condenser chamber can be removed as a solid plug after partial defrost. Residual water can be removed via the solenoid drain valve (manually operated from either the *Manual* or *Home* screens) situated under the front of the Condenser chamber behind the Drain Access Panel (see figure 1).

CAUTION: Do not attempt to open the condenser door for about an hour after defrost has been selected. This may cause damage to the condenser door 'O' ring.

5.0 CREATING / EDITING A PROGRAM

Security level : Supervisor only

A new program is created by editing an existing program and by saving the modified program under a new name. When creating a new program for the first time, use the program called "Prog 1" which has been installed into the Controller memory prior to shipping. To load Prog 1, follow the instructions below:

- a) Press the MENU printed key (see figure 2)
- b) Press the PROGRAMMER button. The *Programmer Menu* screen will be displayed.
- c) Press the PROGRAMS button. The *Load/Save Program* screen will be displayed.
- d) Press the **file name** field. A list of program names will appear in the Options Menu. From the list, press the name of the program to be edited.
- e) Press the green RETURN key. The display returns to the *Load /Save* screen and the **file name** field now displays the name of the program that has been selected.
- f) Press the LOAD button. At this stage, the selected program can either be run or modified. To edit the program, press the EDIT button. Details of the program will appear in the form of a table (referred to as the *Editor Screen*). Each column of the table represents a segment of the freeze drying process and each row describes the freeze drying conditions. Individual cells (denoted SP cells) define the temperature or pressure set points for any particular segment. The top row of cells (referred to as 'segment headings') define the segment name (e.g., freezing, primary drying etc) and duration (hours:minutes:seconds).

To configure the segment headings follow the instructions below:

- a) Press the segment heading that must be modified. A box displaying data about the segment will appear. To change the segment name press the **segment** field. Use the keyboard to input the required name (see figure 2(e)). Press the green RETURN key. The *Editor* screen reappears, showing the new segment name.
- b) To change the segment duration press the **Duration** field and use the keyboard (figure 2(d)) to input the required time (hours: minutes : seconds). Press the green RETURN key. The *Editor* screen reappears, showing the new segment name and duration.

Repeat for any segment heading as necessary.

Note : Changing the duration will not be permitted if the “Ramp @ ” function has been selected previously anywhere in that segment.

Note: Any value entered on the keypad must be within the capability range of the freeze dryer. If an invalid number is entered, the display value will turn red and a new number must be entered.

To configure the segment SP cells follow the instructions below:

- a) Press the SP cell that must be modified. A box displaying data about the cell will appear. Press the **Type** field. A list of optional functions will be displayed. The choice of functions available include Dwell, Step, Ramp and Ramp@. These function are described in more detail in Table 5.

Note: The first column of SP cells can only be specified as a Step.

- b) Select the function that is required and press the green RETURN key.
- c) Depending on the function selected, rate and temperature set point values can then be modified by pressing the appropriate field and entering the value on the numeric keypad (refer to Table 5). Press the DONE button to update the program table (the set point data and SP code is displayed in each cell) .

Table 5: Function Descriptions and Coding

Function Name	Function Description	SP code	Set point fields
Dwell	Temperature set point is held for duration of segment	D	None
Step	Temperature ramps to temperature set point as fast as possible	S	Temperature
Ramp	Temperature ramps to temperature set point at a constant rate over the duration of the segment	R	Temperature
Ramp@	Temperature ramps to temperature set point at specified ramp rate	R@	Rate (/hr) Temperature

5.1 SAVE / SAVE AS

To save the updated program under the same file name after editing is complete, or to save the program as a new file name, follow the procedure below. To insert or delete segments prior to saving, see sections 5.2 and 5.3 respectively.

- a) From the *Editor* screen, press the OPTIONS button on the printed keypad (see figure 2(a)).
- b) To save the edited program under the same file name press the SAVE button.
- c) To save the edited program under a new file name, press the SAVE AS button. The *Save As* screen will appear.
- d) Press the **File Name** field and enter the new file name on the keypad.
- e) Press the green RETURN key and the OK buttons to confirm.

5.2 INSERTING A SEGMENT

To add a new segment to the freeze drying program, follow the procedure below:

- a) From the *Editor* screen, press the segment heading that will proceed the new segment you wish to insert. A box displaying data about the segment will appear.
- b) Press the INS SEG key. The *New Segment* screen will appear.
- c) Press the **Segment** field and use the keyboard to type in the segment name.
- d) Press the green RETURN button. Press the OK button on the *New Segment* screen. A column will then appear in the program table, representing the new segment.
- e) Configure the new segment as per section 5.0.

To save the updated program under the same file name after inserting a segment, or to save the program as a new file name, refer to section 5.1.

5.3 DELETING A SEGMENT

To remove a segment from the freeze drying program, following the procedure below:

- a) From the program editor screen, press the segment header to be deleted. Details of the segment will appear.
- b) Press the DEL SEG button. The *Confirm Delete* screen will appear. Press OK, to confirm delete command.

To save the updated program under the same file name after deleting a segment, or to save the program as a new file name, refer to section 5.1.

Note: The first segment of a program can not be deleted.

5.4 AMENDING THE END-OF-PROGRAM SEQUENCE (EPS)

To amend the set points in the end-of-program sequence, first select the *EPS* screen.

a) Automatic EPD: To amend the pressure rise limit, press the field labelled '**mbar/s**'. Enter the required rate (in scientific notation) on the numeric keypad and press the green RETURN button. To amend the drying time programmed for EPD, press the field labelled '**hrs**'. Enter the required value on the numeric keypad and press the green RETURN button. The amended values will be displayed on the *EPS* screen.

Note: There is no standard setting for the pressure rise rate. An appropriate value should be determined by the user by experiment.

b) Secondary Drying: To amend the temperature set point for secondary drying, press the field labelled '**°C**'. Enter the required temperature on the numeric keypad and press the green RETURN button. To amend the duration for secondary drying, press the field labelled '**hrs**'. Enter the required duration in hours on the numeric keypad and press the green RETURN button. The amended values will be displayed on the *EPS* screen.

c) Automatic Backfill: To amend the backfill pressure, press the field labelled '**mbar**'. Enter the required pressure (in scientific notation, absolute pressure) on the numeric keypad and press the green RETURN button. The amended values will be displayed on the *EPS* screen.

Note: Any value entered on the keypad must be within the capability range of the freeze dryer. If an invalid number is entered, the display value will turn red and a new number must be entered.

6.0 DATA LOGGING

To log process data, a standard 3.5" disc must first be inserted into the disc drive located behind the hinged flap directly below the touch panel (refer to figure 2(a)). The equipment is factory configured to automatically record all process parameters (including chamber and condenser vacuum, condenser and product shelf temperatures, isolation valve and alarm status) after a program cycle is started. Data logging is automatically stopped when the program cycle is complete. Data is logged to disc as an ASCII file (.ASC), which can be imported into most spreadsheet applications for further interrogation after logging is complete.

Note:

1. Always use a new formatted floppy disk for logging
2. Do not use the same disk for recording other types of data.
3. Do not use the same disk for more than one month.
4. Never remove a floppy disk while logging is in progress.

CAUTION: Removing the disc while the data is logging (on line) may cause damage to the equipment.

6.1 CHANGING LOGGING CONFIGURATION

Several data logging functions (e.g., archive interval, file type/name) are factory set. However, the logging configuration can be changed if necessary, as follows:

- a) Press the MENU printed key.
- b) Press the LOGGING button. The *Logging* Menu will appear.
- c) Press the SETUP button. The *Logging Setup* screen will be displayed, giving a summary of the logging configuration. The default setting for the field labelled 'logging' will display **on event**, meaning that logging will start and finish automatically as described above. No other settings can be changed until this field is set to **off** from the drop down menu.

Once the logging is set to **off**, the other settings can be altered by pressing the appropriate field and either selecting an option from the Options Menu or inputting the required value on the keypad. In both cases, press the green RETURN button to accept any selection. Ensure that the SAVE button is pressed to confirm any alterations.

6.2 LOGGING MONITOR

The logging monitor facility can be used to view the current logging status, including media size, free space and free running time. This screen can be accessed as follows:

- a) Press the MENU printed key.
- b) Press the LOGGING button. The *Logging* Menu will appear.
- c) Press the MONITOR button. Logging can also be interrupted from this screen by pressing the OFFLINE button. The disc can then be safely removed.

CAUTION: Removing the disc while the data is logging (on line) may cause damage to the equipment.

7.0 MANUAL OPERATION

CAUTION: Ensure the user is fully trained before manually operating the freeze dryer. Manual operation can bypass process interlock, which may cause damage to the equipment.

Security level : Supervisor

Most equipment components can be manually operated if required. For manual operation follow the instructions below:

- a) Press the menu printed key and select the USER SCREENS button. The User Screens menu will appear.
- b) Select the MANUAL button. The *Manual Operation* screen will display a list of components that can be controlled manually in both condenser and drying chambers.

From this screen, pressure and temperature set points and the positions of system valves can be changed by pressing the appropriate field and either selecting an option from the menu or inputting the required value on the keypad. In both cases, press the green RETURN button to accept any selection.

Note: Some of the above functions can also be manually controlled from the *Home* screen (see section 4).

Note:

Some components have safety interlock to avoid damage to the vacuum system or injury to personnel.

Note: A set point value can only be inputted that is within the capability range of the freeze dryer. If an invalid number or value is entered, the display value will turn red and a new number must be entered.

8.0 ALARMS

The freeze dryer is fitted with a number of alarms that can be used for fault diagnosis and to warn the operator of any faults that may have occurred during a program cycle. If an alarm is activated the alarm panel will flash red and display the code corresponding to the last alarm that was triggered. A number is also given showing the total number of alarms that are active as a ratio of the number of alarms that are still to be acknowledged (e.g., a number of 3/2 means there are 3 active alarms, two of which have been acknowledged).

If an alarm is activated the freeze dryer automatically aborts the current program, closes the vacuum valve and drives the shelf temperature to -20°C . A volt free contact is also given for remote indication of the alarm condition (mounted on the framework at the rear of the drying chamber). Connection details are shown on drawings 7705 and 7788 for the LS60 and LS40 respectively (see Appendix 2). The relay will remain energised until all alarms are acknowledged (see section 8.1).

Note: The alarm marked * in Table 6 is display only.

Note: All alarms will automatically clear when the fault is removed. However, all alarms are logged on the *Alarm History* screen and have to be acknowledged (see below).

A summary of alarm codes and descriptions is given in the Table 6 below.

Table 6. Alarm Codes and Descriptions

CODE	DESCRIPTION	CAUSE
TRIP-VACPUMP	Failure of Vacuum pump	CB2 tripped
TRIP-FRIDGE	Failure of either refrigeration system	CB3 or CB7 tripped
TRIP-FLUID	Failure of fluid pump	CB6 tripped
TRIP-HP 3	Overpressure on drying chamber refrigeration	HP3 pressure switch tripped*

CODE	DESCRIPTION	CAUSE
FAIL-DRY APG	Failure of drying chamber pirani gauge	APGX1 calibration out of limits/ filament failure
FAIL-COND APG	Failure of condenser chamber pirani gauge	APGX2 calibration out of limits / filament failure.
FAIL-HI PRESS	Evacuation time in drying chamber out of limits	Vacuum pump or vacuum valve failure, system leak.
FAIL-CONDTEMP	Condenser temperature high	Condenser refrigeration fail. High load.
FAIL-DRYTEMP	Shelf temperature out of limits	Drying chamber refrigeration / heater fail. Temperature control valve fail. Program requirements outside of instruments capability.
RTDFAIL-FLUID	Failure of fluid temperature sensor	RTD1 failure / calibration out of limits
RTDFAIL-COND	Failure of condenser temperature sensor	RTD2 failure / calibration out of limits

8.1 ALARM ACKNOWLEDGEMENT

Security level: Supervisor only

To acknowledge an alarm, follow the instructions below:

- Press the alarm panel. The Alarms menu will be displayed.
- Press the ACK button to acknowledge individual alarms or the ACK ALL button to acknowledge all alarms. If ACK ALL is selected, a separate screen will appear asking the operator to confirm the acknowledgement.

8.2 ALARM HISTORY

Security level: Operator or Supervisor

The *Alarm History* screen displays a list of alarm conditions and events, showing when they occurred, and if appropriate, when they were cleared.

8.3 ALARM NOTE

Security level: Operator or Supervisor

The Note facility allows an operator-defined text message to be added to the alarm history as follow:

- From the Alarms menu press the NOTE button. The *Add Note* window will appear.
- Press the field labelled '**Your note**'
- Enter the note on the key pad (maximum 16 characters) and press the Green RETURN button to confirm.

The note is then added to the alarm history, where it is displayed along with its time of entry.

8.4 ALARM HISTORY ARCHIVE

Security level: Operator or Supervisor

The Archive facility permits the current alarm history to be saved in ASCII format to floppy disc. To use the Archive facility, follow the instructions below:

Note: In order to avoid the possibility of loss of logging data it is strongly recommended that archiving is performed with normal logging turned off (see section 6.1).

- a) From the Alarms menu, press the ARCHIVE button. The Alarm Archive window will be displayed.
- b) The field labelled **File Name** shows the default of YYMMDDHH.ALH, which the instrument supplies automatically. To change this name, press the field and enter the required name on the keyboard. The file extension is always .ALH (not editable).
- c) Press the OK button when the correct name has been entered.

If required the field labelled '**Date Format**' can be edited in a similar fashion.

9.0 MAINTENANCE

WARNING: Isolate the freeze dryer from the electrical supply before you start maintenance work, so that it cannot be operated accidentally.

WARNING: Dispose of oil and components safely.

CAUTION: Take care to protect sealing faces from damage.

9.1 MAINTENANCE PLAN

The plan below details the minimum maintenance operations necessary to maintain the freeze dryer in normal use. Instructions for each operation are given in the sections shown. The required frequency of maintenance will depend on how often the freeze dryer is used and type of product. If necessary, adjust the maintenance plan accordingly to your experience.

Table 7: Maintenance Plan

OPERATION	FREQUENCY	REFER TO SECTION
Check the vacuum pump oil level	Weekly	9.2
Change the oil mist filter element	6 Monthly	9.3
Inspect the oil drain kit	Monthly	9.4
Change the vacuum pump oil	6 monthly	9.5
Service the vacuum pump	Yearly	9.6
Check condition of door seals	Weekly	9.7
Monitor the drying chamber silicon fluid level	Weekly	9.8
Check cleanliness of both refrigeration systems heat exchangers	Monthly	9.9

9.2 VACUUM PUMP OIL LEVEL

Check that the pump oil level is between the MIN and MAX markers on the bezel of the sight glass. The oil must be clean and transparent. Refer to manufacturers literature for more information.

9.3 OIL MIST FILTER ELEMENT

Change the element as described in the instruction manual for the oil mist filter supplied.

9.4 OIL DRAIN KIT

Inspect the oil drain kit as described in the instruction manual.

9.5 CHANGE VACUUM PUMP OIL

Remove the right hand side panel from the condenser unit.
Use the procedure described in the instruction manual to drain the oil from the pump.

9.6 VACUUM PUMP SERVICE

The vacuum pump must be removed from the freeze dryer in order to carry out a full service. To remove the pump first remove the right hand side panel from the condenser unit. Open the drain access panel and remove the two screws retaining the pump tray to the support framework. Carefully disconnect the vacuum pipe, mist filter and oil return kit and lift the

pump out of the framework. Inspect and clean the vacuum pump inlet filter, gas ballast control, oil sight glass and motor fan cover, as described in the pump instruction manual. When refitting, ensure that all fittings are correctly reconnected to the vacuum pump.

9.7 DOOR SEALS

Routinely inspect the door seals fitted to the drying and condenser chamber.

CAUTION: Do not attempt to open the condenser door if the condenser temperature is below 0°C (this may damage the seal).

9.8 DRYING CHAMBER SILICONE FLUID

Check the silicone fluid reservoir sight glass. This is located on the left hand side panel of the drying chamber. Ensure that the level is between the MIN and MAX markers.

Note: The levels should only be taken when the freeze dryer is switched off and the fluid is at ambient temperature.

9.9 REFRIGERATION HEAT EXCHANGERS

Regularly check the two heat exchangers fitted at the rear of the freeze dryer. Ensure that they are free from the ingress of dust and other foreign objects.

Figure 1. Freeze Dryer layout



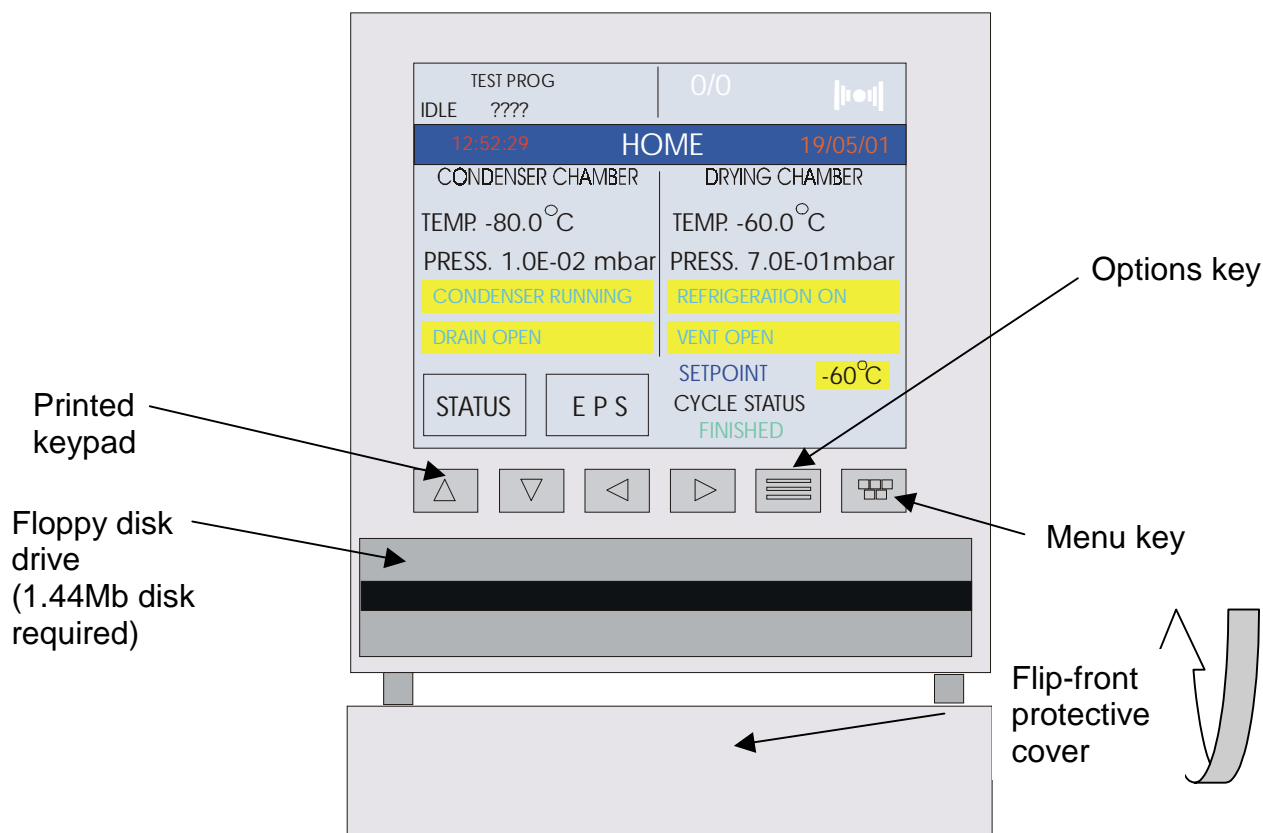
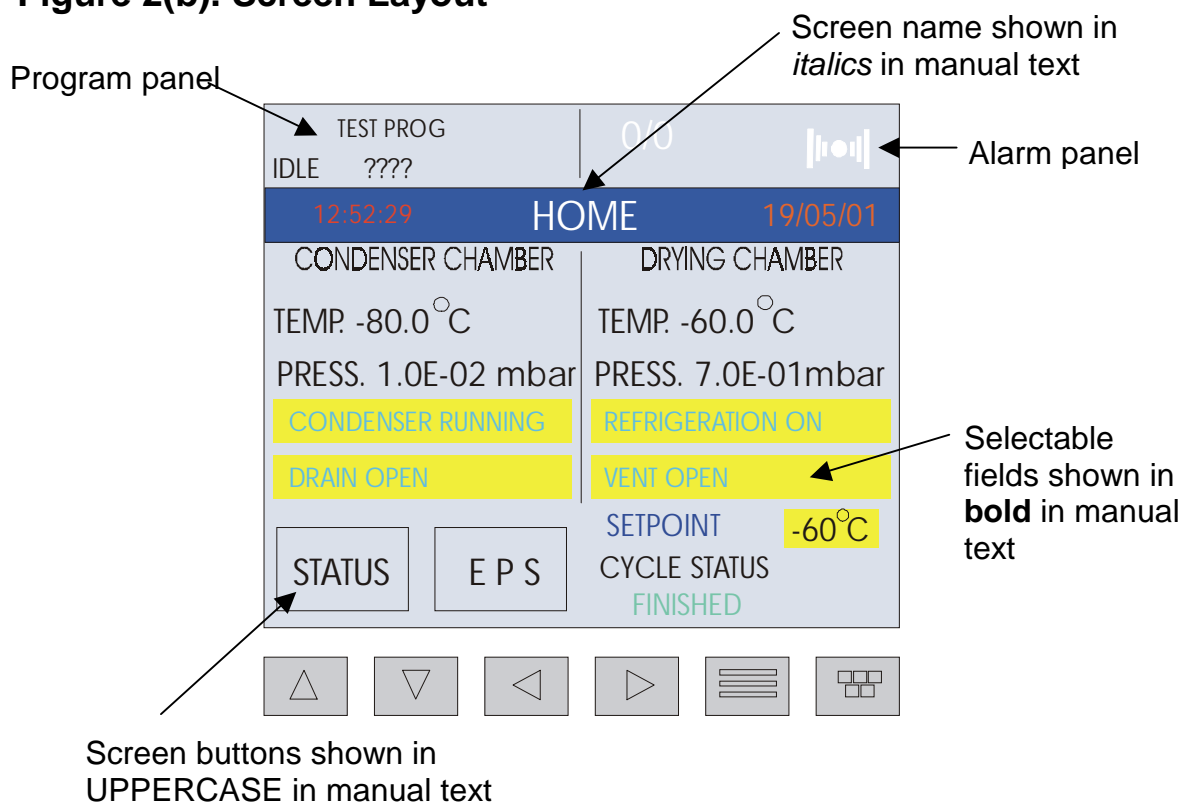
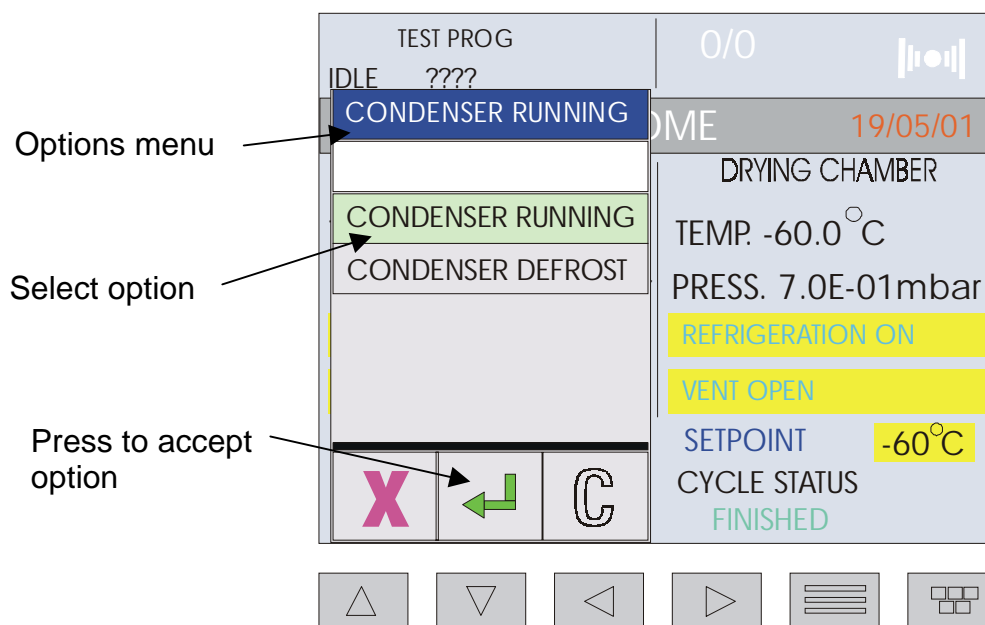
Figure 2(a). Controller Layout**Figure 2(b). Screen Layout**

Figure 2(c). Drop down menu (option list)

Selecting certain fields will reveal a drop down menu with an options list.

**Figure 2(d). Numeric keypad.**

Selecting certain fields will reveal a keypad for entering numeric values.

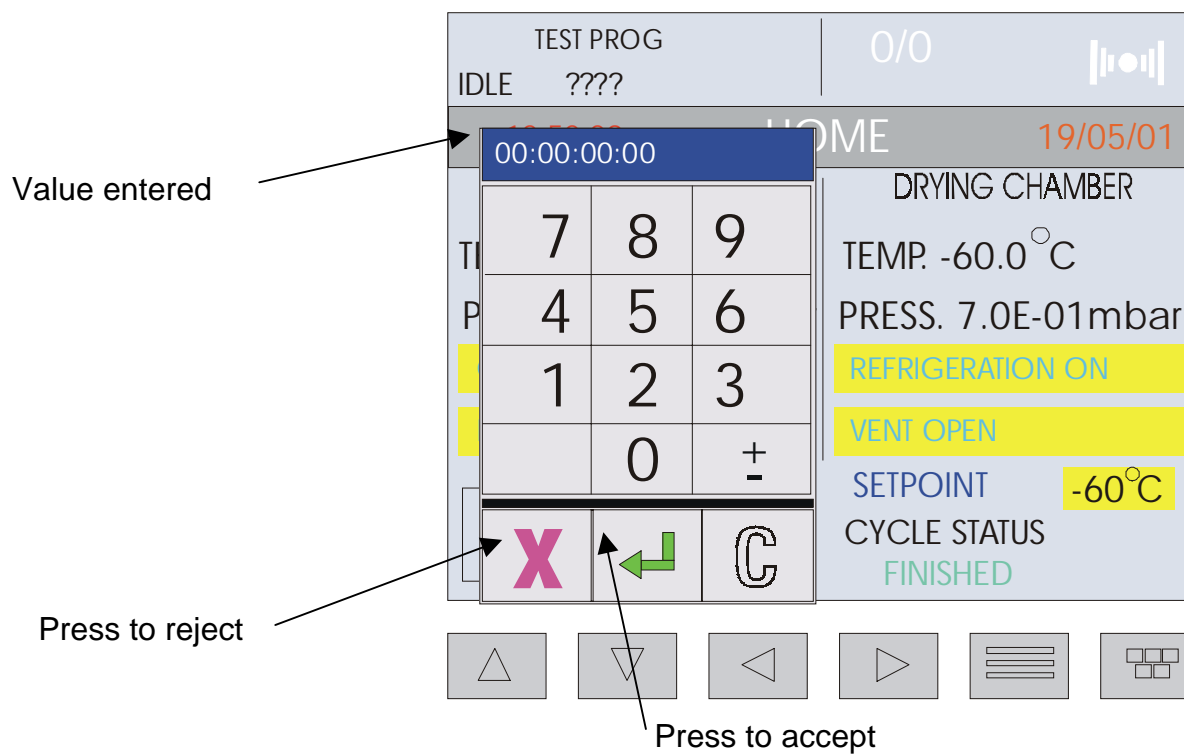


Figure 2(e). Keyboard

Selecting certain fields reveals a keyboard for text entry

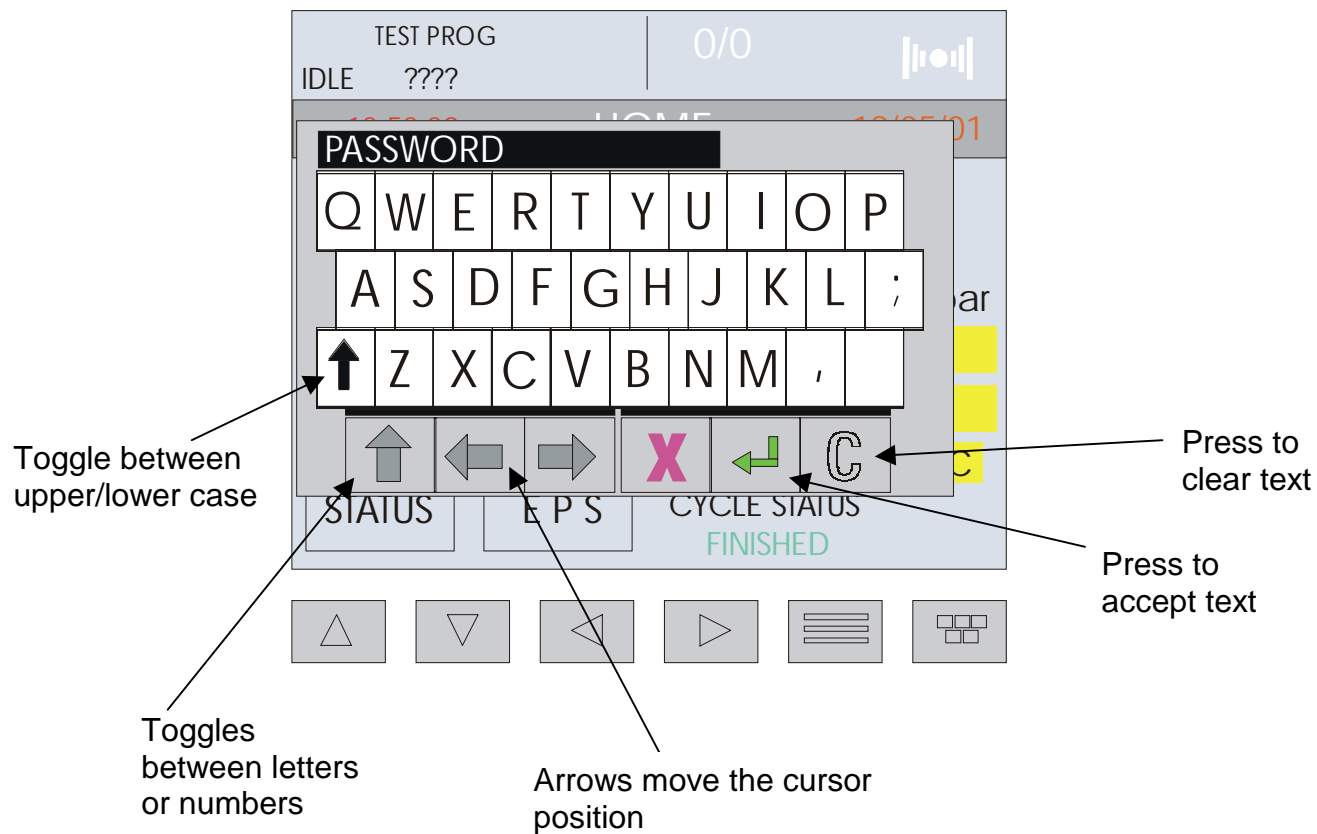


Figure 3. Status screen

The status screen provides a summary of the present condition of the freeze dryer functions. Note: Any conditions highlighted in RED will prevent an automatic program cycle from running.

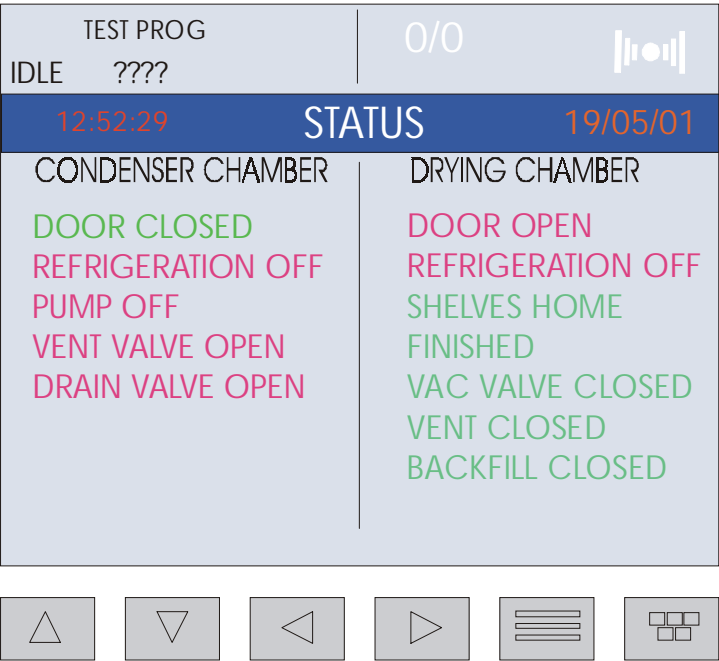
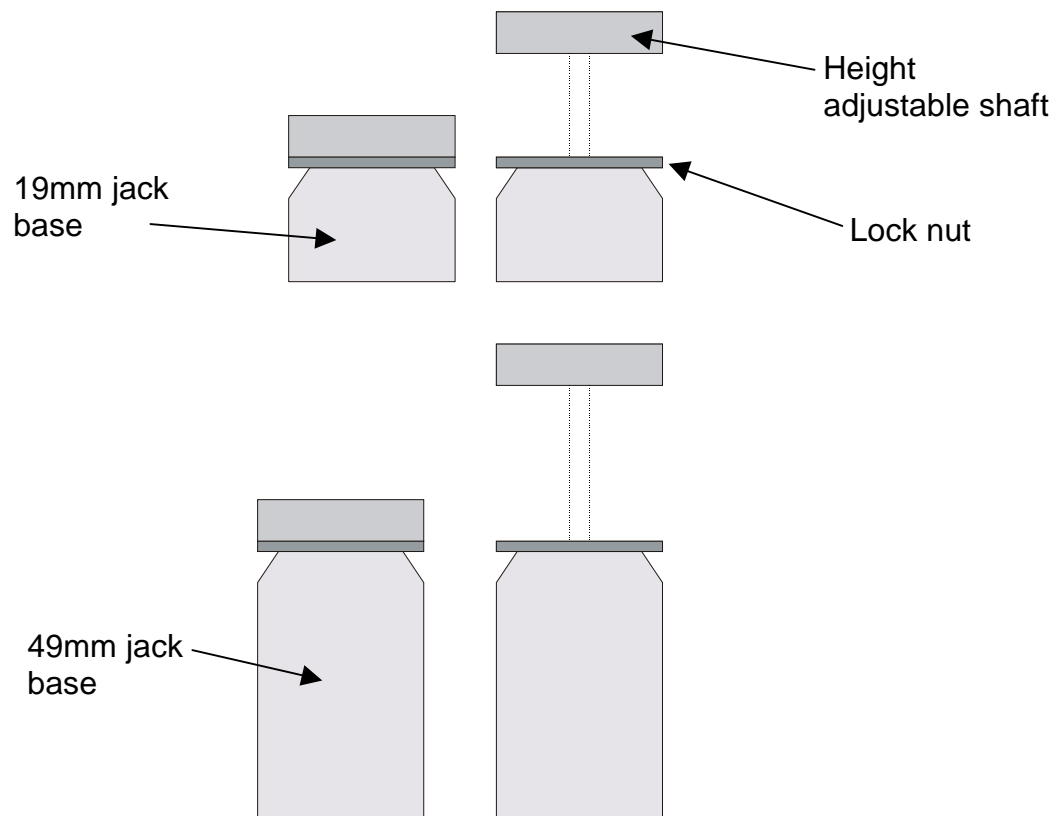
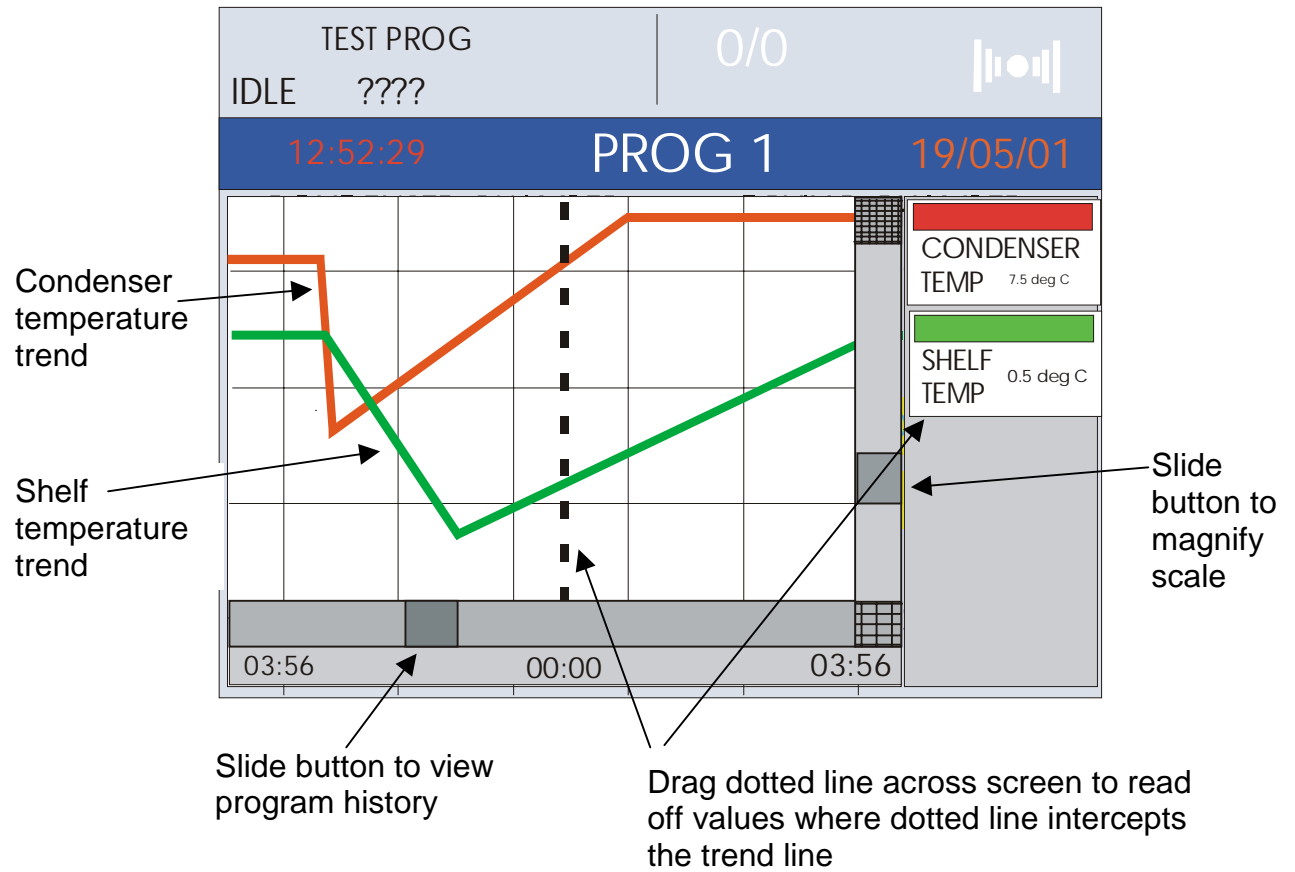


Figure 4. Stoppering Jacks

Vial height	Jack base required	Cap screw shaft length required
32mm – 42mm	19mm	20mm
42mm – 52mm	19mm	30mm
52mm – 62mm	19mm	40mm
62mm – 72mm	49mm	20mm
62mm – 82mm	49mm	30mm
70mm – 90mm	49mm	40mm

Mechanical stoppering jacks must be used when stoppering glass vials. A minimum of three jacks must be used on each shelf (one at each front corner and one equidistant between the rear corners). Ensure that each jack is correctly adjusted, so that it's height equals the height of the vial with a stopper fully inserted.

Figure 5. The pre-plot facility

Appendix 1: Manufacturers Literature

- a) T800/T2900 Visual Supervisor (Eurotherm Controls)
- b) 2500 PID controller (Eurotherm Controls)
- c) 605 series drive unit (Eurotherm Controls)
- d) Cascade refrigeration system (Ernest West & Beynons)
- e) RV12 rotary pump (BOC Edwards)
- f) EMF adjustable gas ballast oil drain kit (BOC Edwards)
- g) EMF10 Oil mist filter (BOC Edwards)
- h) Active pirani gauge (BOC Edwards)
- i) Screw jack assembly (Precision Actuation Systems)
- j) Induction motor (ABB motors)
- k) Pressure transducer (Thermospeed)
- l) Thermostat (Ranco)
- m) Safety interlock switch (Schmersal)
- n) Safety interlock actuator (Schmersal)
- o) Series 102 connector (RS Components)
- p) Fluid circulator pump (Grundfoss)
- q) Safety relay (Pilz)
- r) ML50.100 power supply unit (PULS)
- s) MKS type 1249A valve driver (MKS Instruments)
- t) MKS type 248A/B/C control valve (MKS Instruments)

Appendix 2: List of Drawings

Electrical circuit diagram, 7705 rev A